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**From:** Williams, Jonathan R. [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E099C65734B44D97BBB040607C615812-WILLIAMS, J]  
**Sent:** 10/2/2018 7:48:02 PM  
**To:** Ross, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55d4ef460ed745bdaa975213087b0683-PROSS]  
**CC:** Zinn, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebb6c3c9f28c4542a826017575fcf442-Nicole Y Zinn]  
**Subject:** Tebuconazole Updates Since 16 August 2018  
**Attachments:** Timeline of Tasks 2 Oct 18.docx; 2018-07-30 Tebuconazole - extension request.pdf; Request for a Deadline Extension for Tebuconazole.pdf; 2018-09-14 Bayer 1-Year Progress Report.pdf; 20180912 EPA extension request.pdf; Tebuconazole UPI Study Extension D1.2.docx

Good afternoon Phil,

Per our phone conversation this afternoon, this email contains documents and notes to update you on the tebuconazole registration review case since my last email to you on this subject stamped 2:51 PM, August 16, 2018.

The first attached document is titled Timeline of Tasks 2 Oct 18.docx. This is a copy of my personal notes pasted into a Word document for easier viewing. The first four pages of this document are identical to the document titled Timeline of Tasks 15 Aug 2018.docx, which was attached to the Aug 16 email. The new information begins on page five under the heading Week of 20 Aug. In the time since August 16<sup>th</sup>, there have been the following updates to the case:

- The Bayer cost-sharing consortium asked for an extension to two studies related to the DCI, and to be allowed to conduct the avian dietary toxicity test in lieu of the acute oral toxicity test
  - The request is the attached document titled 2018-07-30 Tebuconazole – extension request.pdf
  - The Agency granted the extension request, but required that the registrant provide more data before being allowed to move to the dietary test (see Request for a Deadline Extension for Tebuconazole.pdf, attached). NB: there is a typographical error in our extension memo: the deadline extension date was listed as 14-April-2018. Given the context of the memo and that this date had already passed, it was understood that the extension was granted to 14-April-2019 (see 2018-09-14 Bayer 1-Year Progress Report.pdf, attached), which is the correct date that the Agency intended to grant.
    - The registrant responded that they would try to submit more data to support their claim, but also referenced another registration review case related to another triconazole class of chemical in which they were allowed to move to the dietary study (see Week of 3 Sep 18, 9/4 in the Timeline document attached)
      - After consultation with EFED, we have decided that these two cases are not the same, and that the circumstances that let the registrant move forward with the dietary test then do not apply here
- In the week of 17 Sept 2018, on 9/17, the Bayer consortium submitted data to meet several requirements related to the DCI, three voluntary submissions, and a 1-year progress report (attached: 2018-09-14 Bayer 1-Year Progress Report.pdf)
- The UPI cost-sharing consortium also asked for an extension request for deadlines related to 12 studies from the DCI (see 20180912 EPA extension request.pdf, attached; NB: this memo lists the companies in the UPI cost-sharing consortium, and these are the same eight targets of the petitions that to listed in your call). They also asked for clarity on the number of study sites needed to satisfy the requirements of GLDN 875.2100. This has been an ongoing conversation with this registrant group and you and I can discuss this further if you'd like.
  - We intend to grant the extension request and provide guidance on the number of study sites in a memo that is currently with EFED for review. A copy of that draft memo is attached (Tebuconazole UPI Study Extension D1.2.docx). Some of the new deadlines will be beyond the furthest deadline listed in the

original DCI, but we expect to be able to move forward with the registration review timeline without delay or extension.

- The UPI group has also begun making submissions to meet the requirements of the DCI. Specifically, they have submitted three protocols for review and indicate that they are working to produce the required data.

This summarizes the major milestones for the case. Please let me know when you would like to meet to discuss my notes further. Feel free to reach out with any questions.

Best wishes,  
Jon

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